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HOGAN & HARTSON LLP IP GROUP, COLUMBIA SQUARE 555 THIRTEENTH STREET, N.W. WASHINGTON, DC 20004			EXAMINER GOTTSCHALK, MARTIN A	
			ART UNIT	PAPER NUMBER
			3626	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/682,644

Applicant(s)

FITALL ET AL.

Examiner

Martin A. Gottschalk

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-30 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-30, and 32-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. Claims 1-12, 14-30, and 32-38 are pending. Claims 13 and 31 have been cancelled. All pending claims have been amended.

Claim Rejections - 35 USC § 112

2. The rejections in the previous Office Action made under 35 USC section 112 are hereby withdrawn.

Claim Rejections - 35 USC §101

3. The rejections in the previous Office Action under 35 USC section 101 are hereby withdrawn.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abdoh (US Pat# 6,654,207, hereinafter Abdoh) in view of Knight (PG Pub# US 2002/0099570, hereinafter Knight).

A. As per claim 1 Abdoh discloses a system for health related data collection (Abdoh: col 2, lns 54-63), correlation (Abdoh: Fig 4, reads on "Comorbidity") and diagnosis (note the diagnoses under the column labeled "CONDITION") comprising:

a database configured for storing data (Abdoh: col 3, lns 1-16);

and

wherein the database (though not a server coupled to the database, see below) is configured for gathering

at least four types of data (Abdoh:

Fig 1, reads on PATIENT SATISFACTION;

Fig 2, reads on FUNCTIONAL HEALTH;"

Fig 3, reads on PCS and MCS;

Fig 4, reads on Comorbidity.)

from at least one profile subject (Abdoh: Figs 1-4, note the item labeled
"PATIENT)

over one or more communication links (Abdoh: col 3, Ins 17-18, reads on
"telephone";

wherein at least two types of the at least four types of data relate to personal
data for the at least one profile subject selected from the group of:

data from at least one profile subject relating to personal health care for
the at least one profile subject (Abdoh: col 2, Ins 56-59);

data from at least one health care provider relating to personal health care
for the at least one profile subject (Abdoh: col 4, Ins 45-53);

data from the at least one profile subject relating to personal perceptions
of interactions by the at least one profile subject with health care
providers;

data from the at least one profile subject relating to health care behavior
for the at least one profile subject;

and

data from at least one third party relating to the health care behavior of the
at least one profile subject;

wherein at least two of the at least four types of data relate to the vascular blood
pressure of the profile subject (Abdoh: Fig 4, the Examiner considers several of
the items under the column labeled "CONDITIONS" to be types of data relating to
the vascular blood pressure of the profile subject, e.g. "Peripheral Vascular
Disease"; "Cerebrovascular Disease"; "Myocardial Infarct"; "Congestive Heart
Failure.");

and

wherein the system combines the at least four types of data to create a
correlated vascular blood pressure health profile of the profile subject that can be
used to diagnose at least one vascular blood pressure related condition (Abdoh:
Fig 4, note the Examiner considers "comorbidity" to be a form or correlation, and
as such the conditions noted in the previously are being correlated in the sense

that they are being noted to occur simultaneously in the same patient – i.e. the patient shows comorbidity for these conditions which relate to the patient's vascular blood pressure.).

Abdoh fails to explicitly disclose

a server coupled to the database,

wherein the server is configured for gathering at least four types of data from at least one profile subject over one or more communication links.

However, this feature is well known in the art as evidenced by Knight. Knight discloses a system for recruiting patients for clinical trials, including a database coupled to a secure server for gathering patient data over the Internet (Knight: Figs. 29, items 2902; Fig. 30; [0017]; [0114] – [0122]).

It would have been obvious to one skilled in the art at the time of the invention to combine the teachings of Knight within the system of Abdoh for the purpose of providing a complete computer network system. The motivation for this combination would have been to rapidly receive and provide more complete and secure information to health care providers and patients regarding treatment options available (Knight: [0004]), thus improving the general satisfaction of the patient (Abdoh: Fig. 1).

- B. As per claim 2 Abdoh discloses the system of claim 1, wherein
- each of the communication links is selected from the group consisting of
- a telephone communication link (Abdoh: col 3, lns 17-18) and
- a computer communication link.
- C. As per claim 3, Abdoh discloses the system of claim 2, further comprising
- an interactive voice response system configured for gathering data from the at least one profile subjects and providing the responses from the at least one profile subjects to the server (Abdoh: col 3, lns 14-16).
- D. As per claim 4, Abdoh discloses the system of claim 1, wherein the server is further configured for
- storing the gathered data in the database (col 3, lns 40-46).
- E. As per claim 5, Abdoh discloses the system of claim 1, wherein the server is further configured for:

prompting the at least one profile subject over the communication link with questions (Abdoh: col 3, Ins 32-47) directed to the personal health care (Abdoh: col 2 Ins 56-59, reads on “clinical and health outcome”) of the at least one profile subject;

and

receiving responses from the at least one profile subject over the communication link in response to the questions (Abdoh: col 3, Ins 39-41).

F. As per claim 6, Abdoh discloses the system of claim 5, wherein the server is further configured for:

prompting the at least one subject for updated data relating to the personal health care for the at least one profile subject;

and

receiving responses from the at least one profile subject over the network communication link in response to the questions.

Claim 6 is rejected for the same reasons given above for claim 5. The Examiner considers the questions and the responses to them referenced in claim 5 to be a form of "updated data".

G. As per claim 7, Abdoh discloses the system of claim 1, wherein the server is further configured for:

prompting at least one health care provider for medical records relating to the at least one profile subject over the communication link;

and

receiving data from the at least one health care provider over the communication link (Abdoh: col 4, lns 45-53).

H. As per claim 9, Abdoh discloses the system of claim 1, wherein the server is further configured for:

prompting the at least one profile subject over the communication link with questions directed to the personal perceptions of interactions by the at least one profile subject with health care providers;

and

receiving responses from the at least one profile subject over the communication link in response to the questions (Abdoh: col 2, Ins 59-63).

I. As per claim 10, Abdoh discloses a the system of claim 9, wherein

the prompted questions relate to the personal perceptions of the profile subject with respect to the quality of the medical care and the satisfaction of the medical care (Abdoh: col 2. Ins 59-63: Fig. 1).

J. As per claim 11, Abdoh discloses the system of claim 9, wherein

the prompted questions relate to the personal perceptions of the profile subject with respect to the advice, information, and prescribed treatment by one or more health care professionals (Abdoh: col 2, Ins 59-63, reads on “post-visit treatment outcome”).

K. As per claim 12, Abdoh discloses the system of claim 9, wherein the server is further configured for:

prompting the at least one subject for updated data relating to the personal perceptions of interactions by the at least one profile subject with health

care providers; and

receiving responses from the at least one profile subject over the network communication link in response to the questions.

Claim 12 is rejected for the same reasons given above for claim 9. The Examiner considers the questions on personal perceptions and the responses to them referenced in claim 9 to be a form of "updated data".

L As per claim 14, Abdoh discloses the system of claim 1, wherein the server is further configured for:

prompting the at least one subject for updated data relating to the health care behavior of the at least one profile subject regarding an existing condition;

and

receiving responses from the at least one profile subject over the network communication link in response to the questions.

Claim 14 is rejected for the same reasons given above for claim 5. The Examiner considers the questions and the responses to them referenced in claim 5 to

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be a form of updated data relating to health care behavior (reads on "clinical and health outcome information" in Abdoh: col 2 Ins 56-59).

M. As per claim 15, Abdoh discloses the system of claim 1, wherein the server is further configured for:

prompting at least one third party for records relating to the at least one profile subject of a communication link;

and

receiving data from the at least one third party over the communication link
(Abdoh: col 4, Ins 45-53, references a plurality of health care providers, one of which would be considered to be a third party.).

N. As per claim 17, Abdoh fails to disclose the system of claim 1, wherein the server is further configured for:

prompting the at least one potential profile subject with screening questions over the communication link;

and

receiving responses from the at least one potential profile subject over the communication link in response to the screening questions.

However, these features are well known in the art as evidenced by the teachings of Knight.

Knight discloses a system that presents and gathers the responses to screening questions from patients who are potential subjects for clinical trials (Knight: [0072]; Figs. 1, 2, and 5).

The motivation to combine the teachings of Knight within the system of Abdoh is the same as provided for in claim 1 and are incorporated herein.

O. As per claim 18, Abdoh fails to disclose the system of claim 17, wherein screening the at least one potential profile subject further comprises the server being configured for:

comparing the responses from the at least one potential profile subject with candidate population characteristics;

and

eliminating a potential profile subject based on the comparison.

However, these features are well known in the art as evidenced by Knight.

Knight teaches:

comparing the responses from the at least one potential profile subject with candidate population characteristics (Knight: [0058], population characteristics reads on "...public and private clinical trials in database.");

and

eliminating a potential profile subject based on the comparison (Knight: [0058], reads on "...accept only patients that match 100% of the...criteria." Note that patients not making the specified match percentage are eliminated.].

The motivation to combine the teachings of Knight within the system of Abdoh is the same as provided for in claim 1 and are incorporated herein.

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P. As per claim 19, Abdoh fails to disclose the system of claim 17, wherein screening the at least one potential profile subject further comprises the server being configured for:

comparing the responses from the at least one potential profile subject with candidate population characteristics;

and

classifying a potential profile subject into one or more studies based on the comparison.

However, these features are well known in the art as evidenced by Knight.

Knight teaches:

comparing the responses from the at least one potential profile subject with candidate population characteristics;

and

classifying a potential profile subject into one or more studies based on the comparison (Knight: [0072]; Fig 2, items 4 and 8; Fig 25A).

The motivation to combine the teachings of Knight within the system of Abdoh is the same as provided for in claim 1 and are incorporated herein.

Q. As per claim 20, Abdoh fails to explicitly disclose the system of claim 17, wherein the screening questions further comprise

questions directed to at least one question selected from the group consisting of

contact details,

demographics,

lifestyle,

past chronic conditions,

current chronic conditions,

treatment for current conditions,

and

current medications.

However, this feature is well known in the art as evidenced by Knight.

Knight teaches a system wherein the screening questions further comprise:

questions directed to at least one question regarding

demographics (Knight: Fig 4, reads on "Date of Birth").

7. Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abdoh in view of Knight as applied to claim 1 above, and further in view of Chilton et al. (Chilton, Lance; Berger, Jan E.; Melinkovich, Paul; Nelson, Richard; et al. "Privacy Protection of Health Information: Patient Rights and Pediatrician Responsibilities." Pediatrics; Oct. 1999; Vol. 104, No. 4; pp. 973-977; hereinafter Chilton.).

A. As per claim 8, Abdoh in view of Knight fails to disclose the system of claim 7, wherein the server is further configured for:

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prompting the at least one profile subject with at least one permission form authorizing a health care provider to provide one or more medical records relating to the at least one profile subject over a communication link;

and

providing the at least one permission form authorizing the health care provider to provide the one or more medical records relating to the at least one profile subject.

However, these features are well known in the art as evidenced by Chilton.

Chilton discloses the growing use of computerized medical records, and electronic transmission of patient health data; the security risks associated with these methods; and the regulatory constraints being applied to this situation (Chilton: Introductory section and section on "Electronic transmission of Health Data"). Chilton further emphasizes the importance of using signed released forms (i.e. permission forms) as security measures (Chilton: section on "Medical Record Release Forms"), and suggests the use of readily available tools such as electronic signatures in maintaining electronic health record security (Chilton: section on "Access to Medical Records", last paragraph.).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the suggestions of Chilton with the combined teachings of Abdoh and Knight in order to enable the legal release of a patient's medical records by a physician electronically. The motivation for this combination would have been to comply with regulatory requirements for security (Chilton: Introductory section, first paragraph), while not unduly burdening the health care provider or impeding the provision of health care (Chilton: Introductory section, third paragraph).

B. As per claim 16, it is rejected for the same reasons provided for claim 8 above, noting additionally that the Examiner considers a "secondary user" to be a third party (Chilton: section on "Primary and Secondary Uses of Health Data").

The motivation to combine the teachings of Abdoh and Knight is the same as given for claim 8 and is incorporated herein.

8. As per claims 21, 22-30, and 32-38 they are method claims, which repeat the same limitation of claim 1, 4-12, and 14-20 respectively, the corresponding system claims, as a series of process steps as opposed to a collection of elements. Since the collective teachings of Abdoh in view of Knight (for claims 1, 4-7, 9-15, and 17-20), and Abdoh in view of Knight, and further in view of Chilton (for claims 8 and 16) disclose the structural elements that constitute the systems of claims 1, 4-12, and 14-20, it is respectfully submitted that they perform the underlying process steps, as well. As such,

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the limitations of claims 21, 22-30, and 32-38 respectively are rejected for the same reasons given above for claim 1, 4-12, and 14-20 respectively.

The motivation for incorporating the features of Knight within the system of Abdoh is as given above in the rejection of claim 1, and is incorporated herein. The motivation for incorporating the features of Chilton within the combined teachings of Knight and Abdoh is as given above in the rejection of claim 8, and is incorporated herein.

Response to Arguments

9. Applicant's arguments in the response filed 02/13/2006 have been fully considered but they are not persuasive. The arguments are addressed below in the order in which they appear in the REMARKS section beginning on page 10 of the response.

10. The claim rejections under USC 35 sections 112 and 101 are hereby withdrawn.

11. Applicant argues the rejections made under 35 USC section 103.

A. In section I starting on page 11, Applicant essentially recites claim 1 and asserts the references of Abdoh and Knight fail to disclose the features of claim 1, including the amendments which add the limitations referring to a subject's vascular blood pressure.

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The Examiner respectfully disagrees and refers Applicant to the citations and reasons provided above for claim 1.

B. In response to Applicant's argument at the top of page 13 in section I that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, The Examiner refers Applicant to the motivation to combine the references provided above for claim 1, i.e. "to rapidly receive and provide more complete and secure information to health care providers and patients regarding treatment options available (Knight: [0004]), thus improving the general satisfaction of the patient (Abdoh: Fig. 1).

C. In section II on pg 13 of the response, Applicant argues the features of claims 8 and 16 are not disclosed by the Chilton reference. The Examiner respectfully disagrees and refers Applicant to the reasons provided above for the rejection of claims 8 and 16.

D. In response to Applicant's argument on page 13 in section II that there is no suggestion to combine the references, the Examiner recognizes that obviousness can

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only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, The Examiner refers Applicant to the motivation to combine the references provided above for claim 1, i.e. "to comply with regulatory requirements for security (Chilton: Introductory section, first paragraph), while not unduly burdening the health care provider or impeding the provision of health care (Chilton: Introductory section, third paragraph)".

E. As per the rejections of claim 21 and the claims which depend from it, they are substantially similar to claim 1 and the claims depending from it, and Applicant is referred above to the reasons and motivations provided above for the rejections of these claims.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

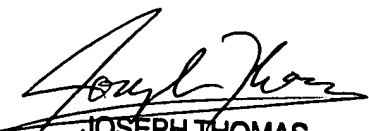
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin A. Gottschalk whose telephone number is (571) 272-7030. The examiner can normally be reached on Mon - Fri 8:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MG
04/14/2006



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